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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,822	BERENSON ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10-12 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10-12 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 08/12/06 is acknowledged.

Claims 1-4, 6-8, 10-12 and 18-24 are pending.

2. Applicant's election of Group I, claims 1-4, 6-8, 10-12 and 18-24 in the reply filed on 08/12/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4, 6-8, 10-12 and 18-24, read on a method for eliminating at least a substantial portion of a clonal T cell subpopulation from a mixed population of T cell comprising exposing a population of cells to one or more pro-apoptotic or growth inhibiting compositions, wherein said exposure induces apoptosis are under consideration in the instant application.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

4. If applicant desires priority under 35 U.S.C. 119 (e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

5. The use of the trademarks have been noted in this application. For example, on pages 11, 23 and 80. It should be capitalized or accompanied by the ™ or ® symbol wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-4, 6-8, 10-12 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 1 is indefinite and ambiguous in the recitation of "induces apoptosis or growth inhibition in at least a substantial portion of at least one clonal T cell population" because the metes and bounds of such "a substantial portion" are ambiguous and unclear. The specification provide no teaching or definition what Applicant considered to be a "a substantial portion" of clonal T cell population present in a mixed population.

9. Claim 7 is indefinite and ambiguous in the recitation of MBP, or MBP 84-102 or MBP 143-168 or SCL-70 or S antigen. Recitation of a protein without providing SEQ ID NO for the protein is indefinite and ambiguous because different laboratories may have the same name for a different proteins.

10. Dependant claims 20-24 recites the limitation " wherein the first agent is an antibody or a fragment thereof and the second antibody agent is an antibody or a fragment thereof". There is insufficient antecedent basis for this limitation in the claims since the base claim 3 does not recites " the first or the second agent".

11. Claims 1-4, 6-8, 10-12 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for eliminating at least a substantial portion of a clonal T cells subpopulation from a mixed population of T cells and further expanding the remaining population of T cells, comprising exposing a mixed population of T cells to surface wherein said surface has attached anti-CD3 and anti-CD28 antibodies and wherein said exposure comprising : (i) culturing said mixed population of T cells with said surface wherein the ratio of surface: cells is high to induce apoptosis in at least a substantial portion of at least one clonal T cells and (ii) further expanding the remaining mixed population of T cells by culturing said remaining T with said surface wherein the ration of surface: cells is low to stimulate the proliferation of said remaining T does not reasonably provide enablement for (i) a method for eliminating at least a substantial portion of a clonal T cell comprising exposing a population of cells to any pro-apoptotic composition , as recited in claims 1 –4 , or (ii) wherein said pro-apoptotic composition comprises any autoantigen as recited in claims 6-8; (iii) wherein said pro-apoptotic composition comprises any agent selected from the group recited in claim 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims as written encompass the genus of any pro-apoptotic or growth inhibiting composition, that can be used in the claimed method.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant discloses a specific method for eliminating at least a substantial portion of a clonal T cell subpopulation from a mixed population of T cells wherein a mixed population of T cells has been exposed first to anti-CD3antibody and anti-CD28 antibody attached to the bead , wherein the ratio of beads to cell is high , for example 3:1 to induce apoptosis in at least a substantial portion of a clonal T cell and further expanded the remaining T cells by exposing to lower beads:cells ration, for example 1:1 (see Example 1 and 4 and Table 1 in particular). Applicant has not taught how to effectively make any pro-apoptotic composition , as recited in claims 1 –4 , or (ii) wherein said pro-apoptotic composition comprises any autoantigen as recited in claims 6-8; (iii) wherein said pro-apoptotic composition comprises any agent selected from the group recited in claim 18 and use them in the recited method. Applicant only disclosed that one skilled in the art would need only routinely experimentation to determined which pro-apoptotic composition can be used in the claimed method. Moreover, it is noted that the claimed method required that the remaining T cells after exposure of a mixed population of T cells to pro-apoptotic composition can be further expanded. In other words , the remaining population of T

cells must be viable and maintained the ability for further expanding i.e. maintain their growth and proliferative capabilities. The instant specification provide no information and guidance as to whether the remaining T cells after exposure of a mixed population of T cells to any pro-apoptotic composition , as recited in claims 1 –4 , or (ii) wherein said pro-apoptotic composition comprises any autoantigen as recited in claims 6-8; (iii) wherein said pro-apoptotic composition comprises any agent selected from the group recited in claim 18 preserved the ability for growth and proliferation as required by the instant claims.

Since the instant fact pattern fails to indicate that representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed a method for eliminating at least a substantial portion of a clonal T cell comprising exposing a population of cells to any pro-apoptotic composition , as recited in claims 1 –4 , or (ii) wherein said pro-apoptotic composition comprises any autoantigen as recited in claims 6-8; (iii) wherein said pro-apoptotic composition comprises any agent selected from the group recited in claim 18 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

13 . Claims 1 and 18 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 9428926.

WO'926 teaches a method for elimination a substantial portion of a clonal T cell subpopulation from a mixed population of T cells comprising exposing a population of cells to pro-apoptotic composition, wherein said pro-apoptotic composition comprised anti-CD3 antibodies in conjunction with IL-2 or IL-4 (see entire document, Abstract in particular).

The reference teaching anticipates the claimed invention.

14. Claims 1-4, 11, 12, 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,352,694 or WO 03/067221 or WO 03/024989 is evidenced by the disclosure of the instant specification on pages 81-83.

US Patent '694 teaches a method of selectively expansion of a specific subpopulation of T cells, comprising exposing a mixed population of T cells to anti-CD3 antibody -anti-CD28 antibody attached to the beads, wherein the ratio of beads to cells in high, i.e. 10:1 and further expanding said cells by culturing said cells with said beads at the ration of bead to cell 1:1 (see entire document, Abstract and columns 9, 19 , 20 and 28 and in particular). US Patent '694 teaches that exposing a mixed population of T cells to said beads, wherein the ration of beads to cells is 3:1 would result in selective elimination of CD8+ T cells which would die by apoptosis (see column 30 and Example 15 in particular). US Patent '694 further teach that selective elimination of a subpopulation of T cells by inducing apoptosis would be useful for further expanding remaining T cells (see column 51 in particular).

WO' 221 teaches a method of selectively expansion of a specific subpopulation of T cells, comprising exposing a mixed population of T cells to anti-CD3 antibody -anti-CD28 antibody attached to the beads, wherein the ratio of beads to cells in high, i.e. 10:1 and further expanding

said cells by culturing said cells with said beads at the ration of bead to cell 1:1 (see entire document, Abstract and pages 24 and 25 and in particular). WO' 221 further teaches administering a composition comprising fludarabine or cyclophoshamide (see page 8 in particular) WO' 221 teaches that exposing a mixed population of T cells to said beads, wherein the ratio of bead to cell is high would result in selective expanding only CD4+ T cell (see overlapping pages 46-47).

It is noted that although WO' 221 does not explicitly disclosed exposing a mixed population of T cell to pro-apoptotic composition, one skill in the art would immediately know that composition comprising fludarabine or cyclophoshamide is pro-apoptotic compositions. Moreover, as is evidenced from the Specification on pages 81-83, exposure mixed population of T cell to high bead: cell ration tends to induce death in at least a portion of T cells. If the prior art structure is capable of performing the intended use, then it meets the claim. For example in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); the following was noted. "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

WO' 989 teaches a method of selectively expansion of a specific subpopulation of T cells, comprising exposing a mixed population of T cells to pro-apoptotic composition (see overlapping pages 16 and 17 in particular). WO' 989 teaches the use of anti-CD3 antibody - anti-CD28 antibody attached to the beads, wherein the ratio of beads to cells in high, i.e. 10:1 and further expanding said cells by culturing said cells with said beads at the ration of bead to cell 1:1 (see entire document, pages 26 and in particular). WO' 989 teaches that using this methodologies , i.e. exposure to high and then low beads:cell ratio, it is possible to selectively expand a selective subpopulation of T cells from the mixed T cell population (see page 50 , 53 and 75 and Table 7 on page 82 in particular).
Although WO' 989 does not explicitly teaches that exposure mixed population of T cells to high bead:cell ration would result in inducing apoptosis in a substantial portion of T cells in the mixed population, said functional properties would be inherent properties of the referenced method. The referenced and claimed method used the same methodology, i.e. exposure a mixed population of T cells to various bead : T cell ratio for selectively expansion of a selected subpopulation of T cells from a mixed population . If the prior art structure is capable of performing the intended use, then it meets the claim. For example in Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999); the following was noted. "Artisans of ordinary skill

may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art". See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Claims 11 and 12 are included because said functional limitation would be inherent properties of the referenced method. It is noted that the referenced method and the claimed method each used the same anti-CD3 antibody anti CD28 antibody attached to the beads to expand the population of T cells. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02.

The references teaching anticipates the claimed invention.

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1, 6, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO'94/28926 in view of the known fact disclosed in the Specification on overlapping pages 27 –28.

The teaching of WO'926 has been discussed, supra.

The claimed invention differs from the reference teaching in that WO'926 does not explicitly teaches a method for eliminating at least a substantial portion of a clonal T cell from a mixed population of T cells comprising exposing said cells to pro-apoptotic composition, wherein pro-apoptotic composition is recited in claims 6, 7 and 8.

The Specification on overlapping pages 27-28 teaches that at the time the invention was made a one of ordinary skill in the art would know that any pro-apoptotic composition, comprising a an agents selected from the group as recited in claims 6, 7 and 8 can be used to eliminating at least a substantial portion of a clonal T cell from a mixed population of T cells. Finding an appropriate pro-apoptotic composition would need only routinely experimentation.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of known fact disclosed in the Specification on overlapping pages 27 –28 to those of **WO'926** to obtain a claimed method for eliminating at least a substantial portion of a clonal T cell from a mixed population of T cells comprising exposing said cells to pro-apoptotic composition, wherein pro-apoptotic composition is recited in claims 6, 7 and 8.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because finding an appropriate pro-apoptotic composition would need only routinely experimentation as taught by fact disclosed in the Specification on overlapping pages 27 –28 and can be further used in the method taught by WO'926. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Semaker. 217 USPQ 1, 5 - 6 (Fed. Cir. 1983). See MPEP 2144.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-4, 6-8, 10-12 and 18-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims of 15 copending applications, i.e. 20060121005, 20050226857, 20050214942, 20050153447, 200500844967, 20040241162, 20040151704, 20040005298, 20030235908,20030124122, 20030119185,20030082806,20030022210,20020119568, 20020058019 is evidenced by the disclosure of the instant specification on pages 81-83.

While the instant and copending claims do differ in certain characteristics, the instant and copending claims appear to be drawn to the same or nearly the same method for selectively stimulating expanding of subpopulation of T cell from the mixed population comprising exposing said mixed population of T cells to a surface, wherein said surface has attached anti-Cd3 antibody- anti-CD28 antibody and wherein the ratio of surface:cells is high and then low.

As is evidenced by the disclosure of the instant specification on pages 81-83 , the exposure of a mixed population of T cells to high bead:cell ratio induces apoptosis in a portion of T cells population present in a mixed population of T cell.

In the interest of compact prosecution, Applicant is invited to indicate whether or not the differences between the instant and each of the copending sets of claims are obvious as on the method of selectively expanding a subpopulation of a T cells from a mixed population of T cells.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-8, 10-12 and 18-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-21 of U.S. Patent No. 6867041 as is evidenced by the disclosure of the instant specification on pages 81-83.

While the instant and claims 17-21 of U.S. Patent No. 6867041 do differ in certain characteristics, the instant and claims 17-21 of U.S. Patent No. 6867041 appear to be drawn to the same or nearly the same method for selectively stimulating expanding of subpopulation of T cell from the mixed population comprising exposing said mixed population of T cells to a surface, wherein said surface has attached anti-Cd3 antibody- anti-CD28 antibody and wherein the ratio of surface:cells is high and then low.

As is evidenced by the disclosure of the instant specification on pages 81-83 , the exposure of a mixed population of T cells to high bead:cell ratio induces apoptosis in a portion of T cells population present in a mixed population of T cell.

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

10/27/06